CyPass Micro-Stent

Töteberg-Harms, M

WATCH IT NOW

This episode of Ophthalmology Insider addresses how new surgical devices will change the management of glaucoma in the future. Moderator Mark Kontos, MD, sits down with Kuldev Singh, MD; Steven Vold, MD; and Arsham Sheybani, MD.

clinical trials, it was common for glaucoma medical therapy to stop approximately 1 month before surgery. In my experience, cessation helps to prevent postoperative hypotony as well as potential choroidal effusion and hypotony maculopathy due, at least in part, to the IOP-lowering effect of topical glaucoma medications in the early postoperative period. If IOP begins to rise postoperatively, it may be advisable to prescribe a prostaglandin analogue rather than an aqueous suppressant in order to maintain the aqueous lake within the supraciliary space. Uveoscleral outflow must be encouraged to ensure successful long-term outcomes with this type of microinvasive glaucoma surgery (MIGS). Further clinical study is required to confirm or contradict this hypothesis.

No. 3. Postoperative care is comparable to that after cataract surgery alone. Patients are typically encouraged to administer prednisolone acetate 1% or difluprednate three to four times a day for 4 to 6 weeks postoperatively. Patients with more ocular inflammation than usual, perhaps related to retained cortex, may continue topical steroid therapy for a longer period of time. Loteprednol is likely a reasonable alternative to prednisolone acetate 1% or difluprednate. Many surgeons also routinely prescribe a topical nonsteroidal anti-inflammatory drug to prevent postoperative pain and cystoid macular edema.

CONCLUSION

Supraciliary surgical options enhance uveoscleral outflow and may potentially lower IOP more than trabecular bypass procedures, especially in patients who have a compromised collector system.[4] With proper surgical technique and thoughtful perioperative care, these MIGS devices have promising safety and efficacy profiles for patients with mild to moderate open-angle glaucoma. At this time, understanding of the supraciliary space, the ideal supraciliary device profile, and perioperative care remains in its infancy. Recent advances are encouraging, however, and continued progress will likely allow surgeons and more of their patients to avoid the risks of filtration blebs in the future.

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2. Emi K, Pederson JE, Toris CB. Hydrostatic pressure of the suprachoroidal space. *Invest Ophthalmol Vis Sci*. 1989;30:233-238.
3. Hoeh H, Ahmed II, Grisanti S, et al. Early postoperative safety and surgical outcomes after implantation of a suprachoroidal micro-stent for the treatment of open-angle glaucoma concomitant with cataract surgery. *J Cataract Refract Surg*. 2013;39:431-437.
4. Vold S, Ahmed II, Craven ER, et al; CyPass Study Group. Two-year COMPASS Trial results: supraciliary microstenting with phacoemulsification in patients with open-angle glaucoma and cataracts. *Ophthalmology*. 2016;123(10):2103-2112.

CyPass Micro-Stent

BY MARC TÖTEBERG-HARMS, MD, FEBO

Most microinvasive glaucoma surgery (MIGS) procedures target trabecular (conventional) outflow into Schlemm canal but cannot completely overcome the problem of impaired subsequent outflow obstruction (ie, collector channels, deep venous plexus, and episcleral veins). The CyPass Micro-Stent (Alcon; Figure 1) is the first FDA-approved MIGS procedure that targets alternative uveoscleral outflow. This system is independent from trabecular outflow, and a negative pressure gradient between the anterior chamber and the supraciliary space is the principle behind this outflow route. The FDA approved the CyPass for implantation through a single clear corneal incision in combination with phacoemulsification cataract surgery plus IOL implantation.

THE PROCEDURE

The CyPass procedure is probably one of the easiest MIGS procedures to learn. Because implantation of the device in the supraciliary space is intuitive, ophthalmologists who are already familiar with angle surgery should be able to incorporate the CyPass into their practice without much difficulty. For those unfamiliar with angle surgery, the greatest challenge is likely visualization of the anterior chamber angle with a goniolens at the microscope in the operating theater. Miosis is achieved with acetylcholine chloride (10 mg/mL). A crucial step in visualization of the anterior chamber angle is turning the patient's head approximately 45° away from the surgeon and tilting the microscope by approximately

(Courtesy of Alcon.)

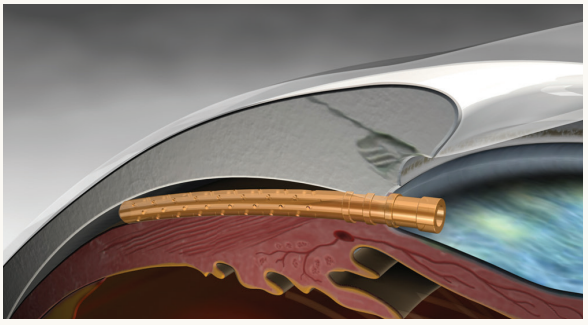


Figure 1. Schematic view of the CyPass Micro-Stent. Note the fluid lake at the end of and around the device.

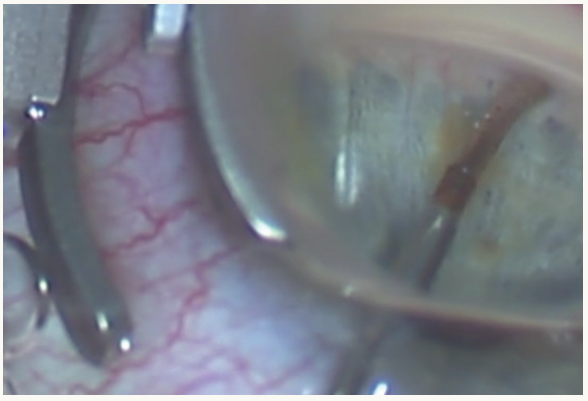


Figure 2. Gonioscopic view through the operating microscope. Approximately one-third of the microstent has been implanted into the supraciliary space.

the same degree in the opposite direction for a temporal approach. A gonioscopic lens with a Thornton ring (eg, Volk Transcend TVG Surgical Goniolens [Volk Optical]) can help the surgeon stabilize and move the eye into the desired direction.

The ophthalmologist introduces the microstent sidewise into the anterior chamber through a corneal incision into the anterior chamber (filled with viscoelastic), turns the implant 90º to align its curvature with that of the sclera, and advances the device toward the opposite side of the eye. He or she should aim directly below the scleral spur (Figure 2). If the guide wire is too close to the iris, the surgeon will observe this tissue moving; if the guide wire is too far away from the iris route, he or she will encounter resistance during implantation. In the correct location, the CyPass glides into the supraciliary space with little to no resistance. The device should be advanced in the supraciliary space but not so far that none of the retention rings is visible in the anterior chamber (Figure 3). The number of rings visualized may vary, depending on the depth of the angle. Ideally, the proximal end of the microstent should be positioned between the pigmented trabecular meshwork and Schwalbe's line. The guide wire is retracted, and the viscoelastic is washed out using irrigation and aspiration (see *Watch It Now* on p. 38).

Patients follow a standard postcataract regimen of topical medication, and glaucoma medication may be discontinued and restarted as needed.

RESULTS

The multicenter, interventional, randomized COMPASS clinical trial included 2 years of follow-up.[1] All patients had primary open-angle glaucoma and a mean diurnal unmedicated IOP between 21 and 33 mm Hg. After cataract surgery, subjects were randomized in a 1:3 ratio to either cataract surgery with IOL implantation alone (control group, n = 131) or in conjunction with CyPass implantation (microstent group, n = 374). Both groups had similar baseline characteristics. Sixty percent of control eyes and 77% of eyes that received the CyPass achieved a reduction in unmedicated IOP of at least 20% at 2 years compared to baseline. IOP decreased by 7.4 mm Hg in the microstent group versus 5.4 mm Hg in the control group ($P < .001$), and 61% of the microstent group and 44% of the control group had an unmedicated IOP between 6 and 18 mm Hg. In addition, 59% of the control subjects versus 85% of microstent subjects were free of medication postoperatively. There were no vision-threatening adverse events related to the microstent, and more than 98% of eyes achieved 20/40 or better BCVA.

In the microstent group, 2.9% of eyes had transient hypotony (IOP ≤ 5 mm Hg); all cases resolved within the first

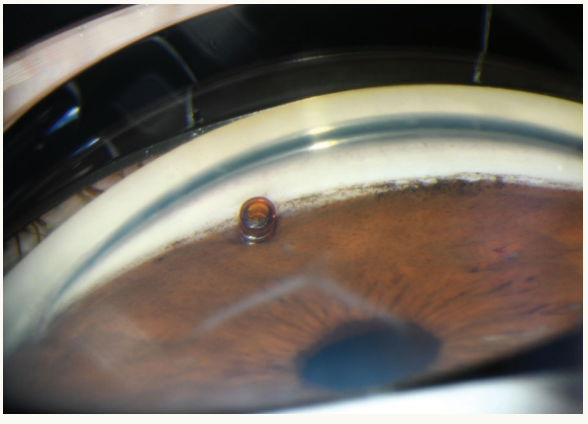
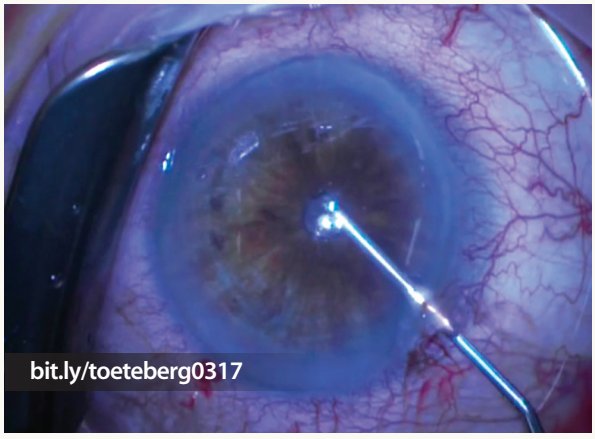


Figure 3. Gonioscopic view 1 week postoperatively. One retention ring is visible in the anterior chamber. The microstent has no contact with the endothelium, and no iris incarceration or contact is evident. A localized cyclodialisis cleft is visible directly around the device.

WATCH IT NOW

Marc Töteberg-Harms, MD, FEBO, demonstrates implantation of the CyPass Micro-Stent.



2 weeks. Whereas hyphema often occurs after trabeculectomy (7.6% in the Tube Versus Trabeculectomy [TVT] study)[2] and with MIGS procedures that bypass the trabecular meshwork (eg, up to 100% after ab interno trabeculectomy with the Trabectome [NeoMedix]),[3] this complication was observed in only 2.7% of eyes that received the CyPass.

1. Vold S, Ahmed, II, Craven ER, et al. Two-year COMPASS Trial results: supraciliary microstenting with phacoemulsification in patients with open-angle glaucoma and cataracts. *Ophthalmology*. 2016;123:2103-2112.
2. Gedde SJ, Herndon LW, Brandt JD, et al; Tube Versus Trabeculectomy Study Group. Postoperative complications in the Tube Versus Trabeculectomy (TVT) study during five years of follow-up. *Am J Ophthalmol*. 2012;153(5):804-814.
3. Jea SY, Francis BA, Vakili, et al. Ab interno trabeculectomy versus trabeculectomy for open-angle glaucoma. *Ophthalmology*. 2012;119(1):36-42.

Subconjunctival Space

Xen Glaucoma Treatment System

BY ERIK L. MERTENS, MD, FEBOPHTH

Microinvasive glaucoma surgery (MIGS) is safer and less invasive than traditional surgery but reduces IOP less dramatically.[1,2] MIGS is characterized by minimal external dissection, a short operating time, a good safety profile, and patients' rapid postoperative recovery. The procedures are logically classified by their target for aqueous outflow: Schlemm canal, the subconjunctival space, or the supraciliary space. The Xen Glaucoma Treatment System (Johnson & Johnson Vision) aims to lower IOP by creating a subconjunctival drainage pathway.

THE SYSTEM

In November 2016, the FDA approved the Xen Glaucoma Treatment System, which consists of the Xen45 Gel Stent and Xen Injector. The implant is a hydrophilic tube composed of a porcine gelatin cross-linked with glutaraldehyde.[3] The biocompatibility properties of gelatin are well established and do not cause any foreign body reaction. The optimal diameter of the tube is based on the laminar flow, as calculated using the Hagen-Poisseuille equation, which predicts that flow depends on tube length, inner diameter, and flow viscosity. In an eye with healthy, mobile conjunctiva, not much outflow resistance comes from the subconjunctival space. To avoid a drop in IOP after surgery, all outflow resistance must come from the tube itself, which is approximately 6 mm long and has an inner diameter of about 45 mm. Flow is 0.02 mL/sec or 1.2 mL/min (at a pressure gradient of 5 mm Hg), thus providing approximately 6 to 8 mm Hg of flow resistance, which essentially eliminates hypotony.[2]

THE PROCEDURE

Surgery is usually performed under a sub-Tenon block, which achieves effective intraoperative akinesia and analgesia without the possibly sight-threatening complications of retrobulbar injections. Typically, surgeons implant the stent after cataract extraction and IOL placement but before removing the viscoelastic, but Xen surgery can also easily be performed as a solo procedure.

Ab interno glaucoma surgery requires excellent gonioscopic visualization for the ophthalmologist to ensure that the angle is open prior to delivering the implant. The preferred placement of the stent is in the superior-nasal quadrant. The surgeon measures 3 mm from the limbus and places two dye marks in the target area. He or she makes the 1.8-mm main incision opposite the target area and creates a 1-mm sideport 60° to 90° away from the main incision.

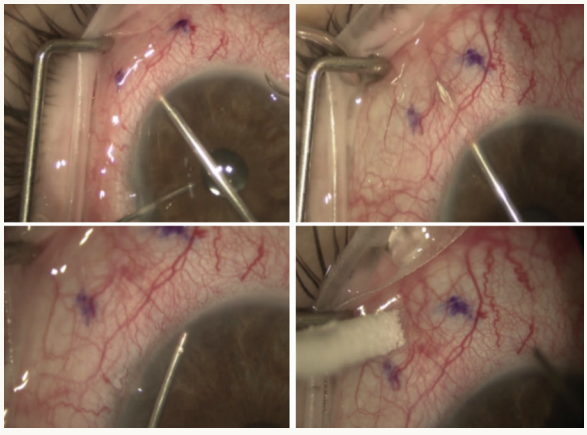


Figure 1. The needle tip exits the sclera ±3 mm from the limbus before delivery of the Xen45 Gel Stent.